

Notice of Allowability

Application No.

09/998,481

Examiner

Joyce Tung

Applicant(s)

BARANY ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview on 10/24/06.
2. ☒ The allowed claim(s) is/are 1-41, 46-86 and 155.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>10242006</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

THE REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance:

Concerning claims 1-41, no prior art has been found teaching or suggesting the method for identifying a mutant nucleic acid sequence from a normal target nucleotide sequences comprising providing a sample containing normal target nucleotide sequence as well as the mutant nucleic acid sequence, performing polymerase chain reaction on normal target nucleotide sequence as well as the mutant nucleic acid sequence with two labeled oligonucleotide primers, forming heteroduplexed amplified products, nicking or cleaving the heteroduplexes products with an endonuclease which preferentially nicks or cleaves at a location one base away from mismatched base pairs, resealing the nicked heteroduplexed products, separating the products from the ligase resealing reaction mixture by size and detecting the presence of the normal target and the mutant nucleic acid sequence in the sample.

Concerning claims 46-86, no prior art has been found teaching or suggesting the method for identifying a mutant nucleic acid sequence from a normal target nucleotide sequences comprising the different steps compared with claim 1 which are providing a sample potentially containing the mutant nucleic acid sequence but not necessarily the normal target nucleic acid sequence and a standard containing the normal target nucleic acid sequence.

Concerning claim 155, no prior art has been found teaching or suggesting the method for identifying a mutant nucleic acid sequence from a normal target nucleotide sequences comprising the several additional steps compared with claims 1 and 46 which are using polymerase with 3'-5' exonuclease activity to remove several bases 3' to the nick, and using a

Art Unit: 1637

polymerase without 3'-5' exonuclease activity and labeled dideoxyterminator to perform mini-sequencing reaction and detecting the presence of the normal target and the mutant nucleic acid sequence by mini-sequencing.

The closest prior art is the reference of Weghorst et al. Weghorst et al. disclose specifically detecting DNA mismatches between heteroduplex strands produced between wildtype and mutation. The method of Weghorst et al. applies the chemical modification of the heteroduplex with reagent that forms a covalent linkage to a mismatched nucleotide in the heteroduplex and detecting the chemically modified mismatched nucleotide. Weghorst et al. do not disclose applying the heteroduplexes, which are nicked or cleaved with endonuclease and resealed with ligase.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
November 7, 2006


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600